

REMARKS

Reconsideration of the above-identified application is requested in view of the foregoing amendments and the following remarks.

I. Amendments to the Claims

Claim 2 is amended to delete the language “wherein said isolated polynucleotide encodes a polypeptide having the biological activity of a cellulase.”

Claim 3 is amended to recite “polynucleotide” and to correct grammar.

Claims 7 and 15 are amended to correct grammar.

No new matter has been added by these amendments.

II. Objections to the Claims

Claim 3 was objected to for reciting “nucleotide” rather than “polynucleotide.” The claim has been amended to address the objection. Withdrawal of the objection is respectfully requested.

III. Rejections under 35 U.S.C. § 112, first paragraph (written description)

Claim 2 was rejected under 35 U.S.C. § 112, first paragraph, as not being supported by an adequate written description for polynucleotides that hybridize to SEQ ID NOs: 1 or 2 under the conditions specified in the claim. In particular, the Examiner asserted that the specification does not contain any disclosure of the structures of all DNAs that hybridize to SEQ ID NOs: 1 or 2, including partial DNA sequences.

Claim 2 has been amended to delete the language “wherein said isolated polynucleotide encodes a polypeptide having the biological activity of a cellulase.” Applicants submit that this amendment obviates the rejection, particularly in view of the USPTO’s Written Description Training Materials published on March 25, 2008. Example 6 (page 21) of the Training Materials relates to claims that recite hybridization conditions. In particular, exemplary claim 3 reads:

An isolated nucleic acid that encodes a protein that binds to the NDG receptor and stimulates tyrosine kinase activity, wherein the nucleic acid hybridizes under highly stringent conditions to the complement of the sequence set forth in SEQ ID NO: 1.

The exemplary claim includes the requirement that the isolated nucleic acid hybridizes to a reference sequence (*i.e.*, the complement of SEQ ID NO: 1) and has a defined function (*i.e.*, binds to the NDG receptor and stimulates tyrosine kinase activity). According to the Training Materials at page 22 (emphasis added):

The disclosure of SEQ ID NO: 1 combined with the knowledge in the art regarding hybridization *would put one in possession of the genus of nucleic acids that would hybridize under stringent conditions to SEQ ID NO: 1*. However, without a recognized correlation between structure and function, those of ordinary skill in the art would not be able to identify without further testing which of those nucleic acids that hybridize to SEQ ID NO: 1 would also encode a polypeptide that binds to NDG receptor and stimulates tyrosine kinase activity.

It is apparent from the Training Materials that the claim language requiring that the isolated nucleic acid hybridizes to a reference sequence *does not* present a written description issue because hybridization methods and their ability to identify structurally-related nucleic acids are well known in the art. It is *only* the combination of the hybridization language with functional language that raises a written description issue.

As amended, pending claim 2 no longer recites functional language, but continues to require that the claimed nucleic acid is as presented in SEQ ID NO: 1 or 2 or hybridizes, under high stringency conditions, to the sequence presented as SEQ ID NO: 1 or 2. Nowhere in the Training Materials is there any indication that such a claim should be found to lack written description. The present disclosure of SEQ ID NO: 1 and 2, combined with the knowledge in the art regarding hybridization, and the description of hybridization conditions in the specification, would put one in possession of the claimed genus of nucleic acids.

For at least the above reasons, Applicants submit that claim 2 as amended is fully support by the specification, as evidenced by the USPTO's own Written Description Training Materials.¹

¹ Note that the above remarks do not apply to the other pending claims, which recite percent identity.

IV. Rejections under 35 U.S.C. § 112, first paragraph (enablement)

Claims 1-5, 7-21, 25-28, and 30 were rejected under 35 U.S.C. § 112, first paragraph, as not being enabled by the specification. In particular, the Examiner asserts that the specification does not enable the skilled person to make and use nucleic acid sequences the share 85-90% identity with the reference sequence.

The rejection is traversed. The Examiner acknowledges that the specification is enabling for a nucleic acid sequence of SEQ ID NO: 1 or 2, a polypeptide of SEQ ID NO: 3, and expression vectors and detergent compositions comprising the same. Since variant polynucleotides and polypeptides, and polypeptide fragments, are expected to possess similar properties with respect to the respective reference molecules, they are made and used in the same manner as the reference molecules. No additional information is required to make and use the claimed variant polynucleotides and polypeptides, or polypeptide fragments. Therefore, the specification is enabling for polynucleotides and polypeptides commensurate with the full scope of the claims.

Referring to Guo *et al.*, The Examiner suggests that only a fraction of variant polypeptides are expected to be active. However, even assuming that some variants or fragments of the present cellulases would be inactive, this observation, alone, should not result in an enablement rejection. First, the pending claims expressly require cellulase activity, thereby excluding inactive molecules. Second, the skilled person is by no means “reduced to the necessity of producing and testing virtually all the possibilities” as asserted by the Examiner (Office Action at page 6). The skilled person would use the vast amount of knowledge available in the art to make and test variants that are likely to retain cellulase activity. Suggesting that a skilled person would randomly make and test variants ignores the level of skill in the art and how skilled persons design and test polypeptide variants. Since the legal question of enablement considers the level of skill in the art, a rejection based purely on the statistics of random mutagenesis is misplaced. This is simply not how the skilled person would make or test variants.

For at least the above reasons, Applicants submit that the pending claims are fully enabled and request withdrawal of the rejection.

V. Rejection under 35 U.S.C. § 102

Claim 15 was rejected under 35 U.S.C. § 102 as allegedly anticipated by Ahsan *et al.* ((1996) *J. Bacteriol.* 178:5732-40).

The rejection is traversed. The standard for lack of novelty, that is, for anticipation, is one of strict identity. To anticipate a claim for a patent, a single prior source must contain all its essential elements. M.P.E.P. § 2131.

Ahsan *et al.* teach a cellulase that shares only 26.2% “best local identity” with SEQ ID NO: 3 (Office Action at 7).² There is no teaching in the reference or other evidence of record to suggest that a fragment of SEQ ID NO: 3 that has cellulase activity reads on the sequence of Ahsan *et al.* Since anticipation requires that a single reference teach all essential elements of a claim, it is clear that Ahsan *et al.* does not anticipate claim 15.

In the absence of any specific teaching in the reference, the Examiner’s argument appears to be based on inherency. However, it is well-settled law that inherency can not be established by mere possibilities. M.P.E.P. at 2112. In the present case, the Examiner has not established even the mere possibility that a fragment of SEQ ID NO: 3 having cellulase activity would read on the sequence of Ahsan *et al.*

For at least these reasons, Applicants submit that the anticipation rejection is without factual or legal basis and should be withdrawn.

² For the limited purpose of addressing the present rejection, Applicants accept the Examiners sequence analysis. However, Applicants reserve the right to challenge or refine this analysis should it become necessary in future prosecution.

VI. Conclusion

Applicants believe that the present application is fully in condition for allowance. Early notice to this effect is earnestly requested. If the Examiner has any questions or believes a telephone conference would expedite prosecution of this application, the Examiner is encouraged to call the undersigned at (650) 846-7614.

Respectfully submitted,

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